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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,578	03/09/2001	Patrick Hwu	2026-4341	6841

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LEYDIG, VOIT & MAYER, LTD.
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6731

EXAMINER

LI, QIAN JANICE

ART UNIT	PAPER NUMBER
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1633

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/803,578	HWU ET AL.	
	Examiner	Art Unit	
	Q. Janice Li, M.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7,8,10,40,41,44-46,52-61,71-76 and 79-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,7,8,10,40,41,44-46,52-61,71-76 and 79-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/19/07 has been entered.

The declaration of Patrick K. Hwu, and the remarks filed 11/15/06 is acknowledged. Claims 1, 4, 7, 8, 10, 40, 41, 44-46, 52-61, 71-76, and 79-93 are pending and under consideration in the instant office action.

The declaration filed on 11/15/2006 under 37 CFR 1.131 is sufficient to overcome the *Beecham* reference.

Unless otherwise indicated, previous objection/rejections that have been rendered moot in view of the declaration, persuasive argument, or new grounds of rejection will not be reiterated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The prior rejection of Claims 1, 7, 40, 41, 71, 72, 79-83, 92, 93 under 35 U.S.C. 102(b) as being anticipated by *Altenschmidt et al* (J Immunol 1997;159:5509-15), is withdrawn in view of the persuasive argument that the allogeneic cells reactive with an endogenous T-cell receptor is not present in the composition taught by *Altenschmidt et al*.

Claims 1, 8, 40, 41, 45, 46, 52, 56, 58, 61, 71, 72, 75, 76, 79-83, 86, 87, 90-93 are newly rejected under 35 U.S.C. 102(b) as being anticipated by *Clay et al* (J Immunol 1999;163:507-13).

Clay et al teach a method for preparing tumor reactive lymphocytes comprising a). providing human peripheral blood lymphocytes (PBL) transduced with a recombinant retroviral vector encoding a chimeric receptor reactive to MART-1 tumor antigen and HLA-A2+ melanoma cells (e.g. the abstract, and page 508), wherein the receptor comprising α chain and β chain of a T cell receptor (e.g. fig. 1), and b). the transduced PBL cells were then co-cultured with irradiated allogeneic PBMC cells (comprising dendritic and B cells) and irradiated allogeneic EBV-B cells, whereby the clonals reactive to the allogeneic cells expanded (indicating the T cells contain an endogenous T-cell receptor reactive to the allogeneic cells). Thus, the co-culture mix contains the claimed T cell, allogeneic cell, and culture medium (a pharmaceutically acceptable carrier) Accordingly, *Clay et al* anticipate instant claims.

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Claims 1, 4, 7, 10, 40, 41, 44, 53-55, 57, 59, 60, 71-74, 79-85, 88, 89, 92, 93 are newly rejected under 35 U.S.C. 102(b) as being anticipated by *Hwu et al* (Cancer Res 1995;55:3369-73, IDS).

Hwu et al. teaches a method for preparing tumor reactive lymphocytes comprising a). providing murine tumor infiltrating lymphocytes (TIL) transduced with a recombinant retroviral vector (Mov- γ) encoding a chimeric receptor reactive with ovarian adenocarcinoma cells (e.g. the abstract, and column 2, page 3370), wherein the chimeric receptor comprising a single chain variable region from mAbs joined to the Fc receptor γ chain and capable of mediating T cell receptor signal transduction and binding FBP (e.g. column 2, page 3369), and b). the transduced TIL cells were co-cultured with allogeneic MC38 colon tumor cells, which results in a large amount of mIFN- γ production (indicating the TIL cells contain an endogenous T-cell receptor reactive with the allogeneic MC38 cells). Thus, the co-culture mix contains the claimed T cell, allogeneic cell, and culture medium (a pharmaceutically acceptable carrier). Accordingly, *Hwu et al* anticipate instant claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on 571-272-0739. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is **(866) 217-9197**. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

**Q. JANICE LI, M.D.
PRIMARY EXAMINER**



Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL
February 26, 2007